Section E. 510 (k) Summary Of Safety And Effectiveness

(The following information is in conformance with 21 CFR 807.92.)

Date Prepared October 6, 2000

Establishment Name and Registration number of submitter

Name: SMV America
8380 Darrow Road
Twinsburg, Ohio 44087

Registration number: 1528274

Contact: Paula McLean

Device name and classification

Classification Code: 90 KPS

Panel Identification: Radiology

Proprietary Name: Quantitative Perfusion SPECT (QPS)
Quantitative Gated SPECT (QGS)

Common Name: Gamma Camera System

Classification Name: System, Emission Computed Tomography

Classification Class: Class II Product

Reason for 510(k) submission New device.

Predicate device
ADAC AutoQuant
QGS (Quantitative Gated SPECT)
QPS (Quantitative Perfusion SPECT)
ADAC CEqual®
Sopha Sophy NXT

Device Description

The QPS and QGS programs are independent, standalone software applications developed by Cedars-Sinai Medical Center for the display and analysis of cardiac SPECT data. The programs will run on the SMV Vision® POWERstation, a processing and display workstation for nuclear medicine images. The QPS and QGS programs take reconstructed tomographic slices of the left ventricle generated from gated and/or non-gated cardiac SPECT studies and display the images along with automatically generated quantification.

QPS analyzes myocardial perfusion by quantifying defect extent and severity using gender and isotope-specific normal limits. 2D and 3D perfusion maps are automatically generated.

QGS analyzes myocardial function by quantifying global and regional ejection fraction, wall thickening, and left ventricular volume at end-diastole and end-systole. 2D and 3D images of perfusion and thickening are generated.

Intended Use

The Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) programs are intended for use in the display and quantification of myocardial perfusion and functional parameters from cardiac SPECT data.

Technological Comparison

The ADAC AutoQUANT, QPS, QGS, CEqual®, and Sopha Sophy NXT Cardiac Software applications have the same indications for use, operate on identical input data, and perform the same analysis and quantification.

Testing

Testing was conducted to demonstrate that each software application functioned as per its specifications. All tests passed with the actual results matching the expected results. Clinical validation has been conducted by Cedars-Sinai Medical Center and published in the Journal of Nuclear Medicine, Vol. 41, No. 4, April 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 9 2001

Paula McLean
Applications Manager
SMV America
8389 Darrow Road
TWINSBURG OH 44087

Re: K003358
QPS (Quantitative Perfusion SPECT) and
QGS (Quantitative Gated SPECT) Software Programs
Dated: October 6, 2000
Received: October 26, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Ms. McLean:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally ~~marketed predicate~~ devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls ~~provisions of the~~ Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS ~~inspections, the Food and Drug Administration~~ (FDA) will verify ~~such assumptions. Failure~~ to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might ~~have under sections~~ 531 through ~~542 of the Act~~ for devices under the ~~Electronic Product~~ Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to ~~proceed~~ to the ~~market~~.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Section F. Indications for Use Form

510(k) Number (if known): K003358

Device Name: Quantitative Perfusion SPECT (QPS)
Quantitative Gated SPECT (QGS)

Indications For Use:

The Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) programs are intended for use in the display and quantification of myocardial perfusion and functional parameters from cardiac SPECT data.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003358